OMB Immediate Displa

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 4-8-03 @ 11:52am
Publication Date 4-10-03
Certifier Jan Cooke

Food and Drug Administration

[Docket No. 03N–0135]

Agency Emergency Processing Under OMB Review; Guidance: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers With Interest in Exporting to Chile

03 APR -8 P12:19

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). FDA is preparing a guidance document intended to notify the public of procedures being implemented by the agency to assist U.S. firms that wish to export dairy products to Chile. FDA is taking this action in response to trade discussions with Chile that have been adjunct to the negotiations of the United States-Chile Free Trade Agreement. FDA is requesting this emergency processing under the PRA because a normal clearance is likely to impede completion of the United States-Chile Free Trade Agreement.

DATES: Fax ~~written~~ electronically mail comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**.]

LB per B. Suhre 4-8-03 ok, per L. Smith

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received,

N1

OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202–395–6974. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: FDA is preparing a guidance document intended to notify the public of procedures being implemented by the agency to assist U.S. firms that wish to export dairy products to Chile. FDA is taking this action in response to trade discussions with Chile that have been adjunct to the negotiations of the United States-Chile Free Trade Agreement. As a result of those discussions, Chile has recognized FDA as the competent food safety authority in the United States to identify U.S. dairy product manufacturers eligible to export to Chile and has concluded that it will not conduct individual inspections of U.S. firms identified by FDA as eligible to export to Chile. Therefore, FDA intends to establish and maintain a list, which will be posted on the Internet and given to Chile, identifying U.S. firms that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or an unresolved warning letter.

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. This information is needed immediately because it will take time to establish a list of U.S. firms that wish to export dairy products to Chile.

Immediate collection of the information will reduce the length of delay before any U.S. firm can actually export their dairy products to Chile without submitting to prior individual inspections from Chile. The use of normal clearance procedures would prolong the time needed to provide guidance on the process for firms to seek inclusion on the referenced list. Delay in resolution of this agricultural trade issue is likely to impede completion of the United States-Chile Free Trade Agreement.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers With Interest in Exporting to Chile

Section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)) authorizes the Secretary of Health and Human Services (the Secretary) to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA.

At a later date, FDA will announce the availability of a final guidance entitled "Establishing and Maintaining a List of U.S. Dairy Product Manufacturers With Interest in Exporting to Chile." The guidance will provide voluntary recommendations on the process for firms that wish to export dairy

products to Chile. Under this guidance, FDA recommends that U.S firms that want to be placed on the list send information to FDA (i.e., name and address of the firm and the manufacturing plant, name and telephone number of contact person, list of products presently shipped and expected to be shipped in the next 3 years, identities of agencies that inspect the plant and date of last inspection, plant number and copy of last inspection notice and, if other than an FDA inspection, copy of last inspection report).

The burden estimates presented below considered the number of U.S. firms that FDA believes produce dairy products and which will be interested in exporting to Chile, which is estimated to total 50. After the first year, FDA believes that approximately five new firms each year will be interested in exporting dairy products to Chile, and thus, being placed on the list.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency of per Response	Total Annual Responses	Hours per Response	Total Hours
50[2]	1	50	1.5	75
5[3]	1	5	1.5	7.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] First year burden.
[3] Recurring burden.

The estimate of the number of firms that will seek to be on the list is based on FDA's current knowledge of the number of U.S. firms that produce dairy products and that will be interested in exporting to Chile. The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms. We estimate that for the first year a firm will require 1.5 hours to read the **Federal Register**, gather the information needed,

and prepare a communication to FDA that contains the information and requests that the firm be placed on the list.

Dated: 4-7-03
April 7, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S